IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9144

Bartle, J. September 20, 2013

Earline T. Vincent ("Ms. Vincent" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Jules Vincent, Ms. Vincent's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered to be eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Drug use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a. & I.22.

In February, 2009, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated June 10, 2000, Dr. Dlabal attested in Part II of claimant's Green Form that Ms. Vincent suffered from moderate aortic regurgitation and underwent surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $657,948.[6]

In the report of claimant's echocardiogram, the reviewing cardiologist, William E. Shell, M.D., noted that the study demonstrated "moderate aortic insufficiency with a jh/lvot of 21%." Under the definition set forth in the Settlement

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4. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

5. Dr. Dlabal also attested that claimant suffered from moderate mitral regurgitation, arrhythmias, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Vincent underwent surgery to replace her aortic valve, the only issue is whether she is eligible for benefits.

Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is greater than 10% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In June, 2009, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for Dr. Dlabal's representation that claimant had moderate aortic regurgitation because her echocardiogram demonstrated only trace aortic regurgitation. In support of this conclusion, Dr. Gillespie explained that:

> The aortic regurg[itant] jet in the parasternal view was minimal with a jet height to LVOTH of no more than 5% on the only study provided for my review done on 6/10/2000. Of note, several subsequent echo[cardiogram] studies reported moderate to severe [aortic regurgitation]. These were not provided for my review.

Based on Dr. Gillespie's finding that claimant did not have at least mild aortic regurgitation, the Trust issued a post-audit determination denying Ms. Vincent's claim. Pursuant to the Rules for the Audit of Matrix Compensations Claims ("Audit Rules"), claimant contested this adverse determination.[7] In

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition (continued...)

contest, claimant argued that her June 10, 2000 echocardiogram provided a reasonable medical basis for a finding of at least mild aortic regurgitation, the "real issue in this case." Claimant also argued that the auditing cardiologist erred because he only considered one regurgitant jet rather than reviewing the entire echocardiogram including multiple frames and heartbeats. In support of her contest, Ms. Vincent submitted the reports of seven additional echocardiograms she contended provided a reasonable medical basis for Dr. Dlabal's Green Form representation. She also submitted declarations by Dr. Dlabal, Manoj Muttreja, M.D., and Issam A. Mikati, M.D., F.A.C.C., F.A.H.A., F.A.S.E. Dr. Dlabal stated, in pertinent part, that:

> 4. At 6:51:31-48 on the 6/10/00 videotape, I found an aortic regurgitant jet with a JH/LVOTH ratio of 21% (0.36/1.69). This regurgitant jet was representative of the regurgitation seen throughout the study, and it represents true aortic regurgitation.
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> 5. Several other factors confirm the presence of at least mild aortic insufficiency (AI) on the 6/10/00 videotape.
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> a.) First, at the time of the echocardiogram, the patient had resting tachycardia, with a heart rate of 99 beats per minute. The presence of a resting tachycardia

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7. (...continued)
of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Vincent's claim.

indicates significant stress on the heart. On the basis of cardiac pathophysiology, this tachycardia strongly suggests the presence of clinically significant AI in this patient. However, due to the tachycardia, the AI will necessarily manifest by echocardiogram as "less severe" than would otherwise be expected due to the fact that, in the presence of tachycardia, the heart spends less time in diastole, which allows less time for the regurgitant jet flow to occur. As a result, the AI "appears" less prominent than expected in a case involving tachycardia. Although AI may appear less prominent due to the presence of tachycardia in this case, AI cannot be less than mild.

b.) Further, the Patient's echocardiogram reports show a clear natural progression of aortic valve disease. In 1998, the Patient had mild-to-moderate AI. In 2007, AI became moderate-to-early severe, and the AI resulted in an aortic valve surgery. Since at least seven (7) other echocardiographic studies confirm the presence of mild AI or greater between 1998 and 2007, it is inconceivable that an echocardiogram performed in 2000 would show less than mild AI, or no AI at all.

c.) On the 6/10/00 videotape, I found more echocardiographic evidence of at least mild AI. This evidence is set forth, as follows:

i. At 6:50:45-51, the pressure half-time (PHT) was 371, which indicates moderate AI by the pressure half-time method. Significantly, the sonographer marked the presence of AI on the screen;

ii. At 6:46:20-25, an aortic cross-section showed a central regurgitant jet which occupied 25% to 50% of the area of the aortic root at the level of the valve; and

iii. At 6:51:0-30, a 3-chamber view showed aliasing, and at 6:44:14-46, a parasternal long-axis view showed significant aliasing. Aliasing indicates turbulence and the presence of high velocity regurgitant jets.

6. Based upon the readily available information, there is incontrovertible and reasonable medical evidence for the finding of at least mild AI on the 6/10/00 videotape.

Dr. Muttreja also reviewed claimant's June 10, 2000 echocardiogram and determined it demonstrated mild aortic regurgitation based on measurements at 6:44:27:15 and 6:44:33:19. Dr. Muttreja also opined that "although diastole only lasted for a short period of time due to Patient's tachycardia, these true regurgitant jets can be discerned by an experienced Cardiologist." Finally, Dr. Muttreja noted that aliasing on claimant's echocardiogram confirmed "the presence of high velocity aortic regurgitation jets and clinically significant aortic regurgitation."

Dr. Mikati similarly found that at 6:44:34:07, the echocardiogram demonstrated "mild to moderate aortic regurgitation, with a JH/LVOTH ratio of 35%." Dr. Mikati opined that this was "representative of the regurgitation seen throughout the study."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Gillespie submitted a declaration in which he confirmed his finding at audit that there was no reasonable medical basis for Dr. Dlabal's representation of moderate aortic regurgitation. Specifically, Dr. Gillespie explained:

> 11. I reviewed the entirety of Claimant's December 10, 2000 echocardiogram tape, including those points in the study identified by Drs. Dlabal, Muttreja and Mikati. After reviewing the study in its entirety, as I did at audit, I do not appreciate aortic regurgitation.
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> 12. The quality of Claimant's December 10, 2000 echocardiogram is suboptimal, but I was able to adequately review it. Based upon the lack of aortic regurgitation on the copy of the tape I reviewed, even taking into account the poor quality, it is unlikely that the Attesting Physician was able to appreciate even mild aortic regurgitation on this study. It is unreasonable to conclude that this study demonstrates even mild aortic regurgitation.
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> 13. Claimant provided a number of echocardiogram <u>reports</u>, but no studies other than the June 10, 2000 study reviewed at audit. While other studies, if available for review, may have demonstrated aortic regurgitation, there is no aortic regurgitation seen on the available June 10, 2000 study. On the basis of the submitted reports and available study, it is not reasonable to conclude that mild aortic regurgitation was present prior to January 3, 2003.
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> 14. Dr. Dlabal asserts that it is reasonable to conclude that the December 10, 2000 study demonstrates mild aortic regurgitation because the presence of

> "resting tachycardia ... strongly suggests the presence of clinically significant [aortic insufficiency]." While *severe* decompensated aortic regurgitation can cause tachycardia, it is incorrect to suggest that the tachycardia is secondary to significant aortic regurgitation in this particular case. Anxiety, fever, anger, dehydration and any number of other causes would be much more likely causes of Claimant's tachycardia.

The Trust then issued a final post-audit determination again denying Ms. Vincent's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement.[8] See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On March 3, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8408 (Mar. 3, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 26, 2010, and claimant submitted a sur-reply on June 22, 2010. Under the Audit Rules, it is within the Special Master's discretion to appoint a

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8. Ms. Vincent also appealed to arbitration the Trust's determination that she ingested Diet Drugs for 60 days or less. Given our disposition, we will dismiss her appeal as moot.

Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Vincent's June 10, 2000 echocardiogram demonstrated at least mild aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Vincent reasserts the arguments made in contest, namely, that the declarations of Dr. Dlabal, Dr. Muttreja, and Dr. Mikati provide a reasonable medical basis for finding that claimant's June 10, 2000 echocardiogram demonstrated at least mild aortic regurgitation. Claimant also argues that the Trust applied a preponderance of the evidence standard rather than reasonable medical basis standard. In addition, Ms. Vincent contends that Dr. Gillespie was biased and that he should have measured claimant's actual level of regurgitation rather than "eyeballing" it given that the difference between Dr. Gillespie's assessment and the minimum JH/LVOTH ratio was only 5%.

In response, the Trust argues that claimant has not met her burden of establishing a reasonable medical basis for her attesting physician's finding that she had at least mild aortic regurgitation. The Trust contends that the "mere submission of multiple reports (from multiple experts) purporting to identify jets of representative regurgitation" is insufficient to meet her burden. Finally, the Trust contends that the auditing cardiologist's use of "eyeballing" was proper because he determined that claimant's aortic regurgitation was "no more than 5%," which does not implicate regurgitation near the 10% threshold.

The Technical Advisor, Dr. Vigilante, reviewed claimant's June 10, 2000 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's

finding that Ms. Vincent had at least mild aortic regurgitation. Specifically, Dr. Vigilante stated, in relevant part, that:

> I reviewed the tape of Claimant's June 10, 2000 echocardiogram.... All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. There was markedly increased color gain during color Doppler evaluation. There was color artifact noted within the myocardium and outside of the heart. In addition, there was abnormal persistence with stuttering of color images in both the parasternal and apical views. However, the Nyquist limit was appropriately set at 70 and 64 cm per second at a depth of 14 cm in the parasternal long-axis view and 64 cm per second at a depth of 14 cm in the apical views.
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> .... The parasternal long-axis view was available for the determination of the aortic regurgitation. However, in all views in which color doppler occurred, there was significant color artifact. Visually, only trace aortic regurgitation was suggested in the parasternal long-axis and apical views. I digitized those cardiac cycles in the parasternal long-axis view during color doppler evaluation. I then measured the JH and LVOTH with electronic calipers in the mid portion of diastole. In spite of significant color artifact, the JH could be determined in the mid portion of diastole in several frames. I determined that the largest representative JH was 0.16 cm. I determined the LVOTH was 2.1 cm. Therefore, the largest representative JV/LVOTH ratio was less than 8%. The ratio did not reach 10% in any cardiac cycle. Therefore, only trace aortic regurgitation could be diagnosed in the parasternal long-axis view on this study. There was no sonographer measurement of the JH. The sonographer measured an LVOTH of 1.69 cm. This measurement was incorrect as it did not reach the posterior portion of the left ventricular outflow tract. I reviewed the time frames documented by the Claimant's medical experts. There was no evidence of aortic regurgitation at time frame 6:44:27:15

> or at time frame 6:44:34:07. An aortic regurgitant jet was noted at time frame 6:44:33:19. However, only trace aortic regurgitation was noted in this time frame. The time frame of 6:51:31:48 documented by Dr. Dlabal occurred in the non-qualifying apical three chamber view. However, only trace aortic regurgitation was suggested even in this view.
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> ....
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> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.b. That is, the echocardiogram of June 10, 2000 demonstrated only trace aortic regurgitation with comments as above. An echocardiographer could not reasonably conclude that mild aortic regurgitation was present on this study when recognizing the inappropriate conduct of the study and when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view even taking into account inter-reader variability.

In response to the Technical Advisor Report, Ms. Vincent argues that the Technical Advisor's reference to the inappropriate conduct of the study is a "red herring" because it was not noted by the auditing cardiologist, occurred despite normal Nyquist and depth settings, and did not preclude a determination of JH in the mid portion of diastole. Claimant also contends that Dr. Vigilante should have measured her aortic regurgitation in the apical long-axis view. Finally, claimant asserts the Technical Advisor failed to use normal clinical judgment and accepted medical standards and failed to properly interpret the inter-reader variability standard.[10]

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10. Claimant also contends the finding of mild aortic

(continued...)

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant that the declarations of Dr. Dlabal, Dr. Muttreja, and Dr. Mikati provide a reasonable medical basis for finding that Ms. Vincent has at least mild mitral regurgitation. Each of these cardiologists opined that claimant's echocardiogram demonstrated at least mild aortic regurgitation and identified at least one frame on the tape where they purport to have interpreted such regurgitation. Dr. Dlabal opined that claimant's tachycardia suggested the presence of clinically significant aortic regurgitation while Dr. Dlabal and Dr. Muttreja both stated that claimant's tachycardia would cause Ms. Vincent's aortic regurgitation to appear less severe.

Dr. Gillespie, however, reviewed claimant's echocardiogram and determined that it demonstrated only trace aortic regurgitation. He also stated that "[w]hile *severe* decompensated aortic regurgitation can cause tachycardia, it is incorrect to suggest that the tachycardia is secondary to significant aortic regurgitation in this case." Notably,

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10. (...continued)
regurgitation in the reports of echocardiograms performed in 1998 and 2000 provides a reasonable medical basis for Dr. Dlabal's representation. It is the reasonableness of his representation based on the June 10, 2000 echocardiogram identified in claimant's Green Form, however, that is at issue in these proceedings. In any event, it does not appear that claimant provided copies of the tapes of these echocardiograms for review by the Trust.

claimant did not substantively dispute Dr. Gillespie's opinion in this regard.

Dr. Vigilante also reviewed claimant's echocardiogram and determined that it demonstrated only trace aortic regurgitation. In addition, Dr. Vigilante reviewed the frames identified by Dr. Dlabal, Dr. Muttreja, and Dr. Mikati and concluded that there was either no evidence of aortic regurgitation or only evidence of trace aortic regurgitation at each of these frames. Neither Ms. Vincent nor her experts identified any particular errors in the measurements made by Dr. Vigilante.[11]

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had at least mild aortic regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate aortic regurgitation cannot be medically reasonable where the auditing cardiologist and the Technical Advisor specifically concluded that claimant's echocardiogram demonstrated a trace JV/LVOTH ratio. Adopting claimant's argument would expand the range for aortic regurgitation and

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11. For these reasons as well, the opinions of her experts do not aid Ms. Vincent in meeting the burden discussed in In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, 543 F.3d 179 (3d Cir. 2008).

would allow a claimant to recover Matrix Benefits when his or her level of aortic regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.[12]

We also reject claimant's argument that the Technical Advisor erred by failing "to make any quantitative measurements in the apical long-axis view." The Settlement Agreement unequivocally requires evaluation of aortic regurgitation to be made in the parasternal long-axis view, and reliance upon the apical long-axis view is permitted only where "the parasternal long-axis view is unavailable." Here, Dr. Vigilante specifically determined that the "parasternal long-axis view was available for the determination of the aortic regurgitation."[13]

Finally, we disagree with claimant that Dr. Gillespie's use of visual estimation was improper. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having mild aortic regurgitation, it does not specify

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12. Moreover, contrary to claimant's contention, the Technical Advisor appropriately took into account the concept of inter-reader variability. He expressly considered, among other things, the opinions of Ms. Vincent's experts and determined, "An echocardiographer could not reasonably conclude that mild aortic regurgitation was present on this study when recognizing the inappropriate conduct of the study and when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view even taking into account inter-reader variability."

13. In any event, Dr. Vigilante noted that "only trace aortic regurgitation was suggested" in the apical views.

that actual measurements must be made on the echocardiogram. As we have explained, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See Mem. in Supp. of PTO No. 2640, at 15 (Nov. 14, 2002). Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of aortic regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously evaluated and accepted in PTO No. 2640.[14]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Vincent's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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14. Claimant's argument fails, in any event, because the Technical Advisor, although not required to, measured the level of Ms. Vincent's aortic regurgitation, which further establishes that claimant is not entitled to Matrix Benefits.